

Serial No.: 10/051,662

Our File No. 31140-B

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: Rodriguez, et al.

Serial No.: 10/051662

Filed: January 18, 2002

For: Prevention of Ovarian Cancer by  
Administration of a Vitamin D Compound

Examiner: R. Cook

Group Art Unit: 1614

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**AMENDMENT AND RESPONSE**

Applicants submit this Amendment and Response after the interview conducted on August 24, 2004. Claims 35-39, 45, 46, 49, 55-59 and 65-73 are pending in the present application as of the prior amendment.

Applicants submit that even if the Need reference were to be considered as pertinent as the Office has previously stated, the claims directed to higher dosages of Vitamin D (e.g., claims 37, 38, 55, etc.) are distinguishable over the low dosage of the Need reference. Applicant understood the Examiner to indicate that the higher Vitamin D dosages could distinguish those claims over the Need reference even under the Office's view of the Need reference, as Need provides no motivation to use higher dosages of Vitamin D.

Moreover, based on the discussions with the Examiner, applicants have amended claim 45 to reflect further that the regimen is contraceptively effective. The Office has granted numerous patents to regimens that are contraceptively effective, and applicants disclose such regimens at page 19, line 26 to page 20, line 4. Need certainly provides no motivation to combine Vitamin D and progestins as in such regimens of claims 45-46 and 49.

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On the basic issue of the pertinence of the Need reference as to any the claims, Applicants submit herewith the Declaration of Dr. Rodriguez, one of the inventors of the present application. Dr. Rodriguez explains that from point of view of a person of skill in the art, the Need reference does not disclose any data that would motivate a physician or any scientist to use or develop a composition comprised of a progestin and Vitamin D for any purpose. In fact, the data presented by Need would argue against administering a regimen combining Vitamin D and progestin. Thus, because each and every pending claim distinguishes over the Need reference for purposes of §102, and no motivation exists to use the combination of progestin plus Vitamin D, the claims should be allowable.